REMARKS

Prior to the present Amendment claims 15-18, 21-23, 25-27, and 38-42 were pending. By this Amendment, applicants have amended claims 42. Accordingly, claims 15-18, 21-23, 25-27, and 38-42 are currently pending.

The Invention

The inventors have discovered that mucosal administration of a mixture of a Hepatitis B virus surface antigen (HBsAg) and a second vaccine antigen which is a viral nucleocapsid or a virus-like particle is effective in generating an immune response. The immune response generated is useful for the prevention or treatment of an infection by either hepatitis B virus, or the agent from which the second vaccine antigen is derived. Further, the inventors surprisingly discovered that HBsAg has an adjuvant effect on the second vaccine antigen.

Office Action

On page 2 of the Office Action, claim 42 was rejected under 35 U.S.C. §112, second paragraph. According to the examiner, the recitation of "a method of administering a vaccine antigen" is indefinite because it cannot be determined to whom or what the antigen is administered to. Further, the examiner asserts that the intended effect of the administration of the vaccine antigen is unclear.

Applicants have amended claim 42. As amended, the claim now clearly states that the vaccine formulation is administered to a mammal for generating an immune response. Support for the amendments to the claims can be found in the specification as originally filed, see *inter alia,* page 5, line 24 to page 5, line 9; and example 2.

Accordingly, the rejection of claim 42 under 35 U.S.C. §112, second paragraph is now moot and should be withdrawn.

Claims 15, 16 and 21-23 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Tabor et al. (U.S. Patent No. 4,547,368) in light of Bowen et al. (*Research Virology*, 1992, 143:269-278, abstract only). In addition, claims 17, 25, 27 and 38-41 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over Tabor et al. in light of Bowen et al., and further in view of Rose et al. (U.S. Patent No. 6,153,201) and Hauser et al. (U.S. Patent No. 5,972,346). Claims 15, 18 and 26 were further rejected under §103(a) for allegedly being anticipated by Wands et al. (U.S. Patent No. 5,025,341).

Tabor et al. discloses a vaccine comprising HBsAg and HBcAg for subcutaneous administration. Bowen et al. teaches subcutaneous and nasal delivery of herpes simplex virus vaccine. Rose et al. discloses the administration of HPV VLPs. Hauser et al. discloses vaccine compositions that are administered intramuscularly. Wands et al. discloses fusion proteins containing HBsAg and HCV core proteins.

Applicants respectfully traverse these rejections, and address the rejections together. The present claims are restricted to vaccine formulations suitable for mucosal administration containing HBsAg antigen and a second vaccine antigen which is a viral nucleocapsid or a virus-like particle. There is no disclosure or suggestion in the cited references of a formulation for mucosal administration having HBsAg antigen and a viral nucleocapsid or a virus-like particle.

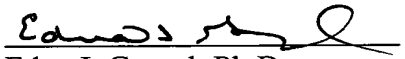
Accordingly, the claimed invention is not anticipated or obvious over the cited references.

Lastly, the examiner's attention is directed specifically to claim 42. Claim 42 is drawn to a method comprising mucosally administering to a mammal a vaccine formulation having a mixture of HBsAg and a viral mucleocapsid or a virus-like particle. There is no disclosure or suggestion in the prior art to do so.

Applicants note with appreciation that the examiner did not reject claim 42 over any prior art references. Therefore, the examiner apparently agrees that claim 42 is free of the prior art.

In view of the above remarks, allowance of the pending claims is earnestly requested. If the examiner has any questions regarding this amendment, the examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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